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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/708,233 | 11/08/2000 | Robert L. Hudkins | CEPH-1157 | 1416 |

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EXAMINER

KIFLE, BRUCK

| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/708,233

Applicant(s)
Hudkins et al.

Examiner
Bruck Kifle, Ph.D.

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 8, 2000
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) 6-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a compound of formula (I), classified in class 540, subclass 545.
- II. Claims 6-11, drawn to a method for enhancing the function of a trophic factor responsive cell, comprising the step of contacting said cell with a compound of formula (I), classified in class 514, subclass 211.01.
- III. Claims 12-16, drawn to a method for enhancing the survival of a trophic factor responsive cell, comprising the step of contacting said cell with a compound of formula (I), classified in class 514, subclass 211.01.
- IV. Claims 17-22, drawn to a method for enhancing the survival of a cell at risk of dying, comprising the step of contacting said cell with a compound of formula (I), classified in class 514, subclass 211.01.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods are known to be practiced by many other compounds including K-252a.

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Groups II-IV raise different issues of patentability.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search required for Group I is not required for Groups II-IV, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Wendy Choi on May 7, 2003 a provisional election was made with traverse to prosecute the invention of group I, claims 1-5. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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i) The phrase "A compound defined by the general formula (I)" is open ended. It is unclear what else is present. The phrase "A compound of formula (I)" is suggested because the structural formula and definitions of the variables fully defines the formula. ✓

ii) The term "substituted" throughout the claims without saying which substituents are intended is indefinite. One skilled in the art cannot say which substituents are permitted and which ones are not. ✗

iii) The term "heteroaryl" is indefinite because it is not known how many atoms are present, how many and what kind of heteroatoms are involved, what size ring is intended and how many rings are present.

iv) In the definition of R^5 and R^6 as "are combined with a nitrogen atom to form a heterocyclic group" is unclear. Is an additional nitrogen present or is the nitrogen of $-NR^5R^6$ intended? The term "heterocyclic" is also indefinite because it is not known how many atoms make up the ring, which atoms are present and what kind of a ring (monocyclic, bicyclic, spiro, fused, bridged, saturated, etc.) is intended.

v) The term "acyl" is unclear. Is only alkanoyl intended or are acyls of other acids also intended (arsenic, sulfuric, phosphonic, etc)?

vi) In the definition of $NR^{23}R^{24}$ as "the residue of an α -amino acid in which the hydroxy group of the carboxyl group is excluded" it is unclear which amino acids are intended. The "heterocyclic group" formed is also not clear (see point iv above).

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis et al. (US 5,461,146). The claims read on the compounds on table 1 (see also attached CAS abstract and structures). The claims read on, for example, the compound II-47 which has the RN 121665-11-0 (which corresponds to the instant compounds wherein in the instant case R¹ represents -CH₂OR⁴⁴; R², W₁ and W₂ are H; X represents a loweralkoxycarbonyl and Y is hydroxy).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (US 5,461,146). The reference teaches structurally similar compounds(see table 1, columns 5-10). The claims differ by requiring a two carbon linker over the methylene linker when one of R¹

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or R^2 represents $-(CH_2)_kR^7$. That is, instant "k" is 2 whereas in the reference it is 1 (see for example compounds II-30, II-3, II-47, II-50, etc.).

It has been long established that structural relationship varying the size of a linking carbon chain - is per se obvious. Specifically, *In re Shetty*, 195 USPQ 753, *In re Wilder*, 195 USPQ 426 and *Ex Parte Gresham* 121 USPQ 422 all feature a compound with a C_2 link rejected over a compound with a C_1 link. Similarly, *In re Chupp*, 2 USPQ 2nd 1437 and *In re Coes*, 81 USPQ 369 have a C_1 link unpatentable over a C_2 link. *Ex parte Ruddy* 121 USPQ 427 has a C_3 link unpatentable over a C_1 link. *Ex parte Nathan*, 121 USPQ 349 found the insertion of a C_2H_4 link obvious. In all of these cases, the variation was per-se obvious and did not require a specific teaching.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

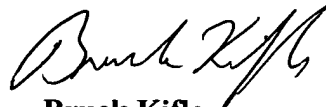
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,306,849. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are embraced by the instant claims. The instant claims differ from the patented claims by reciting a genus that is embraced by the patent. It is obvious to one having ordinary skill in the art to select any of the species of the genus of the patented claims and arrive at the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

May 14, 2003


Bruck Kifle
Primary Examiner
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